



AP/JPW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Ferree

Serial No.: 10/652,842

Group No.: 3738

Filed: August 29, 2003

Examiner: S. Jackson

For: CEMENTED ARTIFICIAL DISC REPLACEMENTS

**CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)**

Mail Stop APPEAL BRIEF  
Commissioner for Patents  
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Dear Sir:

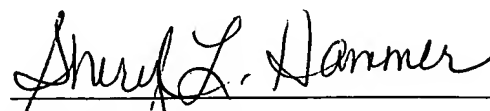
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Corrected Appeal Brief  
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On March 24, 2006.

  
\_\_\_\_\_  
Sheryl L. Hammer



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BOARD OF PATENT APPEALS AND INTERFERENCES

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**APPELLANT'S CORRECTED APPEAL BRIEF**

Mail Stop Appeal Brief  
Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In response to the Notification of Non-Compliant Appeal Brief mailed February 22, 2006, Applicants hereby submit their corrected Appeal Brief.

**I. Real Party in Interest**

The real party and interest in this case is Dr. Bret A. Ferree, Applicant and Appellant.

**II. Related Appeals and Interferences**

There are no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**III. Status of Claims**

The present application was filed with 33 claims. Claims 17 and 18 are canceled by amendment attached hereto. Claims 1 and 20 are the independent claims.

**IV. Status of Amendments Filed Subsequent  
Final Rejection**

An after-final amendment is attached hereto. The amendment to claim 33 is reflected in the Claims on Appeal section of this Appeal Brief.

## **V. Summary of Claimed Subject Matter**

Independent claim 1 is directed to a method of fixing an artificial disc replacement (ADR) to a vertebral endplate. The method comprises the steps of locating a component of the ADR within an intervertebral disc space in spaced-apart relation to the vertebral endplate, and introducing cement between the component and the vertebral endplate. (Specification, page 2, lines 5-10). Claim 11 further includes the step of forming a cement-receiving hole or cavity in a vertebral body (Figure 4, #402). According to claim 12, the component of the ADR includes one or more channels to direct the cement between the component and the vertebral endplate (Figure 1B, #120). According to claim 13, the component of the ADR includes one or more grooves to direct the cement between the component and the vertebral endplate (Figure 6, #602). According to claim 14, wherein the component of the ADR includes a rim that bears against the vertebral endplate, thereby forming a cavity to receive the injected cement (Figure 1A, #112). Claim 15 further includes the steps of forming a passage through the vertebra having the endplate, and injecting the cement through the passage (See Figures 1-4 and accompanying text).

Independent claim 20 is directed to a system including an artificial disc replacement (ADR) configured for placement within a vertebral disc space between opposing vertebral endplates, the ADR comprising a component forming a cavity between the component and one of the vertebral endplates; and a path to fill the cavity with cement (Specification, page 2, lines 20-27; Figure 1B, #120; Figure 6, #602). According to claim 32, the component includes one or more protuberances to create a space for the cement (Specification, page 6, lines 9-14; Figure 3A, #302).

## **VI. Grounds of Objection/Rejection To Be Reviewed On Appeal**

A. The rejection of claims 1-6 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,888,226 to Rogozinski.

B. The rejection of claims 7, 10-11, 14, 15 and 2-28 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,888,226 to Rogozinski in view of U.S. Patent No. 6,595,998 to Johnson.

C. The rejection of claim 8 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,888,226 to Rogozinski in view of U.S. Publication No. 2004/0067876 to Gould.

D. The rejection of claim 9 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,888,226 to Rogozinski in view of U.S. Publication No. 2004/0133280 to Trieu.

E. The rejection of claims 12, 17-19 and 29-33 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,888,226 to Rogozinski in view of U.S. Patent No. 5,340,362 to Carbone.

## VII. Argument

### A. Claim 1

Claim 1 stands rejected under 35 U.S.C. §102(b) over Rogozinski (U.S. Patent No. 5,888,226). In rejecting this claim, the Examiner contends that Rogozinski teaches the steps of locating an artificial disc replacement (ADR) within an intervertebral disc space in spaced-apart relation to a vertebral endplate, and introducing cement between the component and the endplate, referring to column 5, lines 14-15 and column 3, lines 47-53. Appellant respectfully disagrees. According to claim 1, the introduction of cement between the component and the vertebral endplate clearly occurs after the component is located within an intervertebral disc space in spaced-apart relation to the vertebral endplate. This is a point of novelty of claim 1, and is neither taught nor suggested by the '226 patent. Referring to the section cited by the Examiner, column 5, lines 14 and 15 state that a "vertebral attachment member 20 is secured to the vertebra by an known methods, such as by cement, e.g., PMMA, bone in-growth or mechanical means." This neither suggests nor implies that the cement is introduced *after* the component is located within the disc space. Likewise, column 3, lines 47-53 state that, "the disc 10 is composed of the substantially rigid and durable bio-compatible material. The surface may be smooth or provided with undulations or texture. The disc 10 may be formed of plastic, ceramics or metal, or even hydrogel material if enough rigidity is provided." Thus, this passage refers only to composition, and not the steps of Appellant's method as claimed. Given that anticipation

requires the recitation of each and every step of an invention as claimed in a single prior-art reference, anticipation is precluded in this case, since the '226 patent does not teach those steps. Given that claims 2-16 and 19 depend from claim 1, these should be allowable as well, though Appellant will set-forth independent arguments in certain cases.

**B. Claim 11**

Claim 11 adds to claim 1 the step of forming a cement-receiving hole or cavity in a vertebral body. Explicit in this dependent claim is that this hole or cavity is used for the introduction of cement between the component and the vertebral endplate. This claim stands rejected under 35 U.S.C. §103(a) over Rogozinski in view of Johnson, U.S. Patent No. 6,595,998. Apart from the lack of any teaching or suggestion from the prior art to combine these references, Appellant disagrees with the Examiner's conclusion that "the steps of forming a passage through the vertebra having the endplate to inject the cement are inherent." There is nothing inherent about the lack of disclosure. Neither Rogozinski nor Johnson, alone or in combination, teach the steps in combination according to this claim, such that it should be held allowable.

**C. Claim 12**

Claim 12 adds to claim 1 the limitation of an ADR component having one or more channels to direct the cement between the component and the vertebral endplate. This claim stands rejected under 35 U.S.C. §103(a) over Rogozinski, in view of Carbone (U.S. Patent No. 5,340,362). However, in the body of the rejection, the Examiner appears to refer only to a separate tool which is removed before the component is placed in spaced-apart relation to the vertebral endplate. That is, the comments by the Examiner appear only to refer to claim 18, which has been cancelled with the filing of this Appeal Brief. Claims 12, 19 and 29-33 should be deemed allowable on the grounds that they have not been rejected by any substantive argument on the part of the Examiner.

**D. Claim 13**

Claim 13 adds to claim 1 the limitation of the component of the ADR including one or more grooves to direct cement between the component and the vertebral endplate. Although the cover sheet of the rejection indicates that all claims are under rejection, there is no argument that Appellant can find

in the rejection itself to substantiate any lack of patentability. Accordingly, claim 13 appears to simply be allowable over the prior art.

**E. Claim 14**

Claim 14 adds to claim 1 the limitation of a component of the ADR which includes a rim net bears against the vertebral endplate, thereby forming a cavity to receive the injected cement. Again, it must be kept in mind, that this cavity is formed after the component is introduced into the disc space, and prior to cement injection. This claim stands rejected under 35 §103(a) over Rogozinski in view of Johnson. However, in the body of the rejection, the Examiner states that only Johnson purportedly discloses an ADR which "comprises a rim (266) wherein cement is injected under fluoroscopic observation (column 22, line 49). However, this "rim" to the extent that it exists at all, does not meet the claimed limitation of a rim that bears against a vertebral endplate, thereby forming a cavity. Rather, the Board will note that the bone filler 204, shown in Figure 28, flows around stacked wafers, which are at all times fully contained within a vertebral body, and are never associated with the endplate thereof. Accordingly, *prima facie* obviousness has not been established.

**F. Claim 15**

Claim 15 adds to claim 1 the steps of forming a passage through the vertebra having the endplate, and injecting the cement through the passage. Claim 15 stands rejected under 35 U.S.C. §103(a) over Rogozinski in view of Johnson. However, the Examiner states only that "the steps of forming a passage through the vertebra having the endplate to inject the cement are inherent." There is nothing inherent about an entire lack of disclosure. Neither Rogozinski nor Johnson teach nor suggest such steps, such that *prima facie* obviousness could not possibly be established in this case.

**G. Claim 20**

Claim 20 resides in the system, including an ADR, the ADR comprising a component forming a cavity between the component and a vertebral endplate, and a path to fill the cavity with cement. Claim 20 stands rejected under 35 U.S.C. §103 over Rogozinski in view of Johnson. However, neither Rogozinski nor Johnson include, teach or suggest a component forming a cavity between the component

and a vertebral endplate, nor did they disclose a path to fill such cavity with cement. This is despite the Examiner's argument that Johnson allegedly teaches "forming a receiving hole or cavity in a vertebral body," and that "the steps of forming a passage through the vertebra having the endplate to inject the cement are inherent." Given that neither of these is taught or suggested by the cited references, *prima facie* obviousness has not been established. Given that claims 21 through 33 depend from claim 20, these should be deemed allowable as well. Nevertheless, independent argument will be given with respect to claim 32.

#### H. Claim 32

Claim 32 adds to the system of claim 20 a component including one or more protuberances to create the space. Claim 32 stands rejected under 35 U.S.C. §103(a) over Rogozinski in view of Carbone. Although the Examiner's arguments are directed to the use of a separate tool which is removed, there are no arguments whatsoever regarding these protuberances. Accordingly, claim 32, and 33, which specifies that these protuberances are PMMA spacers, are allowable as *prima facie* obviousness has not been established.

#### Conclusion

In conclusion, for the arguments of record and the reasons set forth above, all pending claims of the subject application continue to be in condition for allowance and Appellant seeks the Board's concurrence at this time.

Respectfully submitted,

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Date: March 24, 2006

**APPENDIX A****CLAIMS ON APPEAL**

1. A method of fixing an artificial disc replacement (ADR) to a vertebral endplate, comprising the steps of:  
    locating a component of the ADR within an intervertebral disc space in spaced-apart relation to the vertebral endplate; and  
    introducing cement between the component and the vertebral endplate.
2. The method of claim 1, wherein the component of the ADR is a rigid endplate.
3. The method of claim 1, wherein the component of the ADR is polyethylene or other suitable polymeric material.
4. The method of claim 3, wherein the component articulates with a second component.
5. The method of claim 4, wherein the second component is substantially rigid.
6. The method of claim 5, wherein the substantially rigid component is constructed of titanium, chrome cobalt, or ceramic.
7. The method of claim 1, wherein the cement includes an antibiotic.
8. The method of claim 1, further including the step of preparing a vertebra with hypotensive anesthesia prior to fixing the ADR.
9. The method of claim 1, further including the step of preparing a vertebra with a hemostatic agent prior to fixing the ADR.



10. The method of claim 1, further including the use of fluoroscopy during the step of cementing the ADR.

11. The method of claim 1, further including the step of forming a cement-receiving hole or cavity in a vertebral body.

12. The method of claim 1, wherein the component of the ADR includes one or more channels to direct the cement between the component and the vertebral endplate.

13. The method of claim 1, wherein the component of the ADR includes one or more grooves to direct the cement between the component and the vertebral endplate.

14. The method of claim 1, wherein the component of the ADR includes a rim that bears against the vertebral endplate, thereby forming a cavity to receive the injected cement.

15. The method of claim 1, further including the steps of:  
forming a passage through the vertebra having the endplate; and  
injecting the cement through the passage.

16. The method of claim 1, further including the step of pressing the component against the vertebral endplate until the cement cures.

19. The method of claim 1, further including the step of shaping the vertebral endplate before introducing the cement.

20. A system including an artificial disc replacement (ADR) configured for placement within a vertebral disc space between opposing vertebral endplates, the ADR comprising:

a component forming a cavity between the component and one of the vertebral endplates; and  
a path to fill the cavity with cement.

21. The system of claim 20, wherein the path is formed in the component.
22. The system of claim 20, wherein the path is a channel or groove.
23. The system of claim 20, wherein the component includes a peripheral rim to form the cavity.
24. The system of claim 20, wherein the component is a rigid endplate.
25. The system of claim 20, wherein the component is polyethylene or other suitable polymeric material.
26. The system of claim 20, wherein the component is a rigid endplate.
27. The system of claim 20, further including an instrument for urging the component against the vertebral endplate until the cement cures.
28. The system of claim 20, further including an instrument for injecting the cement prior to insertion of the component.
29. The system of claim 20, further including an instrument for pressurizing the cement following introduction.
30. The system of claim 20, further including an instrument for removing excess, cured cement prior to placement of the ADR.
31. The system of claim 20, further including two components, one proximate to each of the opposing vertebral endplates; and

paths for injecting cement between each component and its respective vertebral endplate.

32. The system of claim 20, wherein the component includes one or more protuberances to create a space for the cement.

33. The system of claim 32, wherein the protuberances are PMMA spacers.

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**APPENDIX B**

**EVIDENCE**

None.

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**APPENDIX C**  
**RELATED PROCEEDINGS**

None.